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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,899	06/27/2003	Lisa M. Donnelly	022956-0218	7787
21125	7590	06/02/2005	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,899

Applicant(s)

DONNELLY ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 10, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/02/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9 and 11-17, drawn to a graft fixation device including an expandable sheet and a sheath expander, classified in class 623, subclass 13.18.
 - II. Claim 10, drawn to an expandable sheath for a graft member, classified in class 606, subclass 72.
 - III. Claims 18 and 19, drawn to a method for fixing a ligament graft in a bone tunnel, classified in class 623, subclass 13.14.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the expandable sheath as claimed in claim 11 does not require the distal end to be closed, and does not require the outer surface of the each sidewall to be concave. The subcombination has separate utility such as a graft ligament anchor (has utility by itself), or, as a scaffold for bone ingrowth.
3. Inventions III and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice

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another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. For example, instead of inserting an expansion plug, the sheath could be press-fitted (interference fit) or screwed within the bone tunnel in order to frictionally engage the graft member. Also, instead of positioning the graft member outside the sheath, the graft member could be disposed within the sheath.

4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product. For example, instead of inserting an expansion plug, the sheath could be press-fitted (interference fit) or screwed within the bone tunnel in order to frictionally engage the graft member. Also, instead of positioning the graft member outside the sheath, the graft member could be disposed within the sheath.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Lisa J. Michaud on Wednesday May 25, 2005 a provisional election was made with traverse to prosecute the invention of I, claims 1-9 and 11-

17. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 10, 18, and 19 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to non-elected inventions.

Claim Objections

7. Claims 1, 2, 5, and 17 are objected to because of the following informalities:
- a. Regarding claim 1, please substitute “side wall” (see line 6) with --sidewall--. Appropriate correction is required.
 - b. Regarding claim 2, please add --radially expandable-- in front of “sheath” (see line 3). Appropriate correction is required.
 - c. Regarding claim 5, please add --of the expandable sheath-- in front of “are joined” (see line 1). Appropriate correction is required.
 - d. Regarding claim 17, please substitute “the sheath expander” (see line 6) with --each sheath expander--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 4-9, 11, 12, and 14-17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hays et al. (US 2002/0072797 A1).

Referring to Figures 24-28, Hays et al. disclose a graft fixation device for fixing a graft member within a bone tunnel (bone tunnel 600), the device comprising: (i) a bioabsorbable (see paragraphs 0091-0092 for a list of bioabsorbable materials) radially expandable sheath (sheath 400) having a substantially closed distal end (e.g., distal tip 409: “substantially closed” is broadly

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interpreted) with at least two sidewalls (sidewalls 405) extending proximally therefrom and defining a central lumen (central lumen 450), each sidewall having a substantially concave outer surface (concave surfaces 410-440) *adapted to seat* (emphasis added to functional language) a graft member (see entire document), and each sidewall being at least partially separated by a longitudinally oriented slot (longitudinally extending fracture regions 490, which may include cut-out areas 406, 452, and/or longitudinal flexion regions 480: see paragraphs 0084 and 0086-0089) extending from a proximal end along a substantial length of each sidewall and terminating at a position proximal to the distal end (see Figures 24-28; see paragraphs 0084 and 0086-0089). With regards to the sheath expander and the functional language associated to it, see threaded sheath expander 700, and the entire document. With regards to claims 4 and 14, see ribs 402. With regards to claims 5 and 15, see tabs 1000. With regards to claims 6, 7, 16, and 17, see threaded sheath expander 700, and paragraphs 0082-0090. With regards to claims 8 and 9, see paragraphs 0091-0092. Paragraph 0090 teach the use of a wide variety of sheath expanders and a kit.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Hays et al. (US 2002/0072797 A1).

Hays et al. disclose the invention as claimed (see 102(b) rejection above). Although Hays et al. disclose tapering distal tip, they did not disclose expressly said distal tip as being bullet-shaped. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have modified Hays et al.'s distal tip 409 to have a bullet (rounded) shape because Applicants have not disclosed that shaping a distal tip to have a bullet (rounded) shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well with either a tapered distal end or a bullet-shaped distal end because both shapes would have permitted the radially expandable sheath to be easily inserted into a bone tunnel.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hays et al. (US 2002/0072797 A1) in view of Simonian et al. (US 6,099,530).

Hays et al. disclose the invention as claimed (see 102(b) rejection above). Although Hays et al. disclose a central lumen, they did not particularly disclose said lumen as receiving a guide wire. However, this is well known in the art. For example, Simonian et al. disclose a radially expandable sheath comprising a lumen (cannulation 138) for receiving a guide wire in order to facilitate implantation of the device (see column 4, lines 27-37). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a radially expandable sheath comprising a lumen for receiving a guide wire, as taught by Simonian et al., with the radially expandable sheath of Hays et al., in order to facilitate implantation of the device.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

May 25, 2005



David H. Willse
Primary Examiner